

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,
et al.,

Defendants.

Civil Action No. 17-6921 (MAS) (TJB)

MEMORANDUM OPINION

SHIPP, District Judge

This action involves a patent covering Plaintiff Merck Sharp & Dohme Corp.'s ("Plaintiff" or "Merck") drug product alvimopan, which is prescribed and sold in the United States under the trademark Entereg[®].¹ Defendants Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc. (collectively, "Teva" or "Defendants") have filed an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"), seeking to commercially manufacture and market a generic version of Entereg[®] and challenging the validity of Plaintiff's patent.

This matter comes before the Court for the construction of claims in one of Plaintiff's patents: U.S. Patent No. 6,469,030 (filed Nov. 29, 2000) (the "'030 Patent"). (ECF No. 51-3.)

¹ Merck's Opening Markman Brief provides the following: "The alvimopan compound was first disclosed in a patent application filed by Eli Lilly in 1992. . . . In 1998, a small start-up company located outside Philadelphia and known as 'Adolor' acquired the rights to alvimopan. . . . Adolor ultimately conceived and reduced to practice alvimopan's use for the treatment of ileus, as set forth in the patents-in-suit." (Merck Opening Br. 5, ECF No. 52.)

The Court, having considered the parties' submissions, and having conducted a Markman Hearing² on December 18, 2018, provides its claim construction as set forth below.

I. BACKGROUND

The '030 Patent, entitled "Methods for the Treatment and Prevention of Ileus," was filed on November 29, 2000, and has an expiration of November 29, 2020. (*See* Teva Opening Br. 4, ECF No. 51.) The '030 Patent "discloses the novel method for treating or preventing ileus by using alvimopan." (Merck Opening Br. 5-6, ECF No. 52 (citing '030 Patent col. 1:13-17, 32:6-7).) The '030 Patent contains twenty-six claims, with claim one as the only independent claim. ('030 Patent col. 28:32-34.) The terms at issue in the instant matter pertain to claim 17, which Merck asserts "recites a method of treating or preventing ileus by administering to a patient an effective amount of alvimopan." (Merck Opening Br. 6 (citing '030 Patent col. 32:6-7).)

II. LEGAL STANDARD

A. Claim Construction

Claim construction is a threshold issue the Court must address before analyzing infringement and/or invalidity. Claim construction is a question of law that the Court decides, not a jury. *See Markman*, 517 U.S. at 391. "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks and citation omitted). "[W]ords of a claim 'are generally given their ordinary and customary meaning.'" *Id.* (quoting *Vitronics Corp. v. Conceptiontronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary

² *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996).

skill in the art in question [(the “POSA”)] at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1313 (citations omitted). A POSA is a hypothetical person who “is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.*

“Claim construction begins with the intrinsic evidence of the patent—the claims, the specification, and the prosecution history—and may require consultation of extrinsic evidence to understand the state of the art during the relevant time period.” *Horizon Pharma Ir. Ltd. v. Actavis Labs., UT, Inc.*, No. 14-7992, 2016 WL 4408990, at *2 (D.N.J. Aug. 17, 2016) (citing *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015)). “[T]he best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history.” *Phillips*, 415 F.3d at 1315 (internal quotation marks and citation omitted). “[P]rior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence.” *V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005) (citations omitted).

An alternate to the plain and ordinary meaning rule exists when the patentee “choose[s] to be his [or her] own lexicographer and use terms in a manner other than their ordinary meaning” *Vitronics Corp.*, 90 F.3d at 1582 (citation omitted). In such a case, the “lexicography governs,” and “[t]he inventor’s words that are used to describe the invention—the inventor’s lexicography—must be understood and interpreted . . . as they would be understood and interpreted by a person in that field of technology.” *Phillips*, 415 F.3d at 1313, 1316 (citation omitted). Accordingly, “the court starts the decisionmaking process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history.” *Id.* at 1313.

Courts may also consider extrinsic evidence, however, that evidence “is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* at 1317 (internal quotation marks and citation omitted). “[I]f the meaning of the claim limitation is apparent from the intrinsic evidence alone, it is improper to rely on extrinsic evidence other than that used to ascertain the ordinary meaning of the claim limitation.” *Bell Atl. Network Servs., Inc. v. Covad Commc’ns Grp., Inc.*, 262 F.3d 1258, 1268-69 (Fed. Cir. 2001) (citation omitted).

B. Prosecution Disclaimer

“Prosecution disclaimer ‘preclud[es] patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.’” *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1359 (Fed. Cir. 2017) (quoting *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003)). Prosecution disclaimer requires that “a claim in a patent as allowed must be read and interpreted with reference to claims that have been cancelled or rejected, and the claims allowed cannot by construction be read to cover what was thus eliminated from the patent.” *Omega Eng’g, Inc.*, 334 F.3d at 1323. The Federal Circuit has, however, “declined to apply the doctrine . . . where the alleged disavowal of claim scope is ambiguous.” *Id.* at 1324; *see also Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1063-64 (Fed. Cir. 2016) (citation omitted) (“The party seeking to invoke prosecution history disclaimer bears the burden of proving the existence of a ‘clear and unmistakable’ disclaimer that would have been evident to one skilled in the art.”).

During prosecution, the Examiner originally rejected the Applicants’³ claims based on the following references: U.S. Patent No. 5,250,542 (filed July 17, 1992) (“Cantrell”) (ECF Nos. 63-6, 63-7); D.J. Mack & J.D. Fulton, *Paralytic Ileus: Response to Naloxone*, 76 Brit. J. Surgery 1101

³ Merck acquired Entereg[®] as part of a series of mergers, and was not the original patent applicant. (Merck Opening Br. 5.) The Court, accordingly, refers to the original patent applicants as the “Applicants”.

(1989) (“Mack”) (Ex. H, ECF No. 54-8); and J.C. Schang & G. Devroede, *Beneficial Effects of Naloxone in a Patient with Intestinal Pseudoobstruction*, 80 Am. J. Gastroenterology 407 (1985) (“Schang”) (Ex. I, ECF No. 54-9). (Ex. 8 (“Application”), ECF No. 53-8.) Regarding Cantrell, the Examiner stated, “Cantrell teaches the utility of his claimed compounds as blockers of mu receptors for treating constipation and regulating gut motility. Constipation and the absence of gut motility are common findings following all types of ileus.” (*Id.* at 4.) The Applicants responded, stating, “Cantrell fails to teach or suggest the treatment or prevention of ileus,” and further stated the Examiner, “mischaracterizes the relationship between ileus and constipation, incorrectly suggesting that constipation is a symptom of ileus.” (Weir Ex. 9 (“Request for Reconsideration”) at 2, 3, ECF. 53-9.) The Applicants additionally iterated, “ileus is completely different than constipation.” (*Id.* at 3.)

Regarding Mack, the Examiner stated, “Mack teaches the administer of the mu opioid receptor antagonist naloxone to treat paralytic ileus in a patient who had previously received morphine sulfate. Paralytic ileus is disclosed to be a frequent complication of many surgeries.” (Application at 4-5.) The Applicants replied, “[T]he terms ‘paralytic ileus’ and ‘constipation’ are mistakenly used synonymously in Mack to describe the same condition. However, as discussed previously, and as is well known in the art, ileus and constipation are not the same condition, and in fact, Mack reports constipation, despite using the term ileus.” (Request for Reconsideration at 4.) The Applicants further stated, “Because Mack incorrectly refers to ileus instead of constipation, the combination of Cantrell and Mack fails to teach all of the elements of the claimed subject matter, and therefore *prima facie* obviousness is not met.” (*Id.*) In distinguishing Mack, the Applicants cited to *Harrison’s Principles of Internal Medicine*, arguing it “unequivocally

show[ed] that the two terms[, ileus and constipation,] do not refer to the same condition.” (*Id.* (citing Harrison’s Principles of Internal Medicine (Isselbacher, et al. eds., 13th ed. 1994))).

Finally, regarding Schang, the Examiner stated, “Schang teaches the administration of naloxone in a patient with intestinal obstruction who had previously undergone a colectomy and had not received exogenous opioid agonists.” (Application at 5.) The Applicants replied, “[S]imilar to that discussed above, Schang fails to remedy the deficiencies of Cantrell in that Schang does not teach or suggest, *inter alia*, the treatment or prevention of ileus. Instead, Schang reports the treatment of intestinal pseudo[-]obstruction, which is not ileus or derived from ileus.” (Request for Reconsideration at 4.)

C. Indefiniteness

“[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). “[D]efiniteness is measured from the viewpoint of a [POSA] . . . at the time the patent was filed.” *Id.* at 908 (citation omitted). “[A] patent must be precise enough to afford clear notice of what is claimed, thereby ‘appris[ing] the public of what is still open to them.’” *Id.* at 909 (alteration in original) (citation omitted). “[T]he definiteness requirement[, however,] must take into account the inherent limitations of language” and a “modicum of uncertainty” is permitted due to those limitations. *Id.* (citations omitted). A patent is presumptively valid, and to demonstrate indefiniteness, an allegedly infringing party must show “by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim” *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008); *N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1579 (Fed. Cir. 1993).

III. DISCUSSION

A. The Court adopts Teva's definition of a POSA

The parties' experts have both stated that their opinions regarding the terms to be construed would likely not change based upon the Court's definition of a POSA. (*See* Decl. of Jonathan Resnick ("Resnick Decl.") ¶ 17, ECF No. 54 ("My opinions expressed below regarding the meaning of 'ileus' . . . would not change if the level of skill were determined to be somewhat higher or lower."); *see also* Decl. of Neil H. Hyman ("Hyman Decl.") ¶ 62, ECF No. 51-1 ("[E]ven if Merck's definition of the skilled artisan were to apply, I reach the same conclusions as to the proper constructions (or indefiniteness) of the identified claim terms and phrases.".) Nonetheless, before reviewing the claims, the Court "must establish the level of skill that a POSA possessed at the time of the invention." *Supernus Pharm., Inc. v. Actavis, Inc.*, No. 14-7272, 2016 WL 901837, at *2 (D.N.J. Mar. 9, 2016) (citing *AllVoice Computing PLC v. Nuance Commc'ns, Inc.*, 504 F.3d 1236, 1240 (Fed. Cir. 2007)). Accordingly, although the definition adopted may not necessarily affect construction of the disputed terms, the Court will define the POSA in the context of the '030 Patent for the purposes of this claim construction. *See Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, No. 10-1376, 2012 WL 2358102, at *4 n.3 (S.D. Ind. June 20, 2012) (finding that determining a POSA was necessary to resolve the dispute even though both parties stated that the issue was not dispositive with respect to claim construction).

Merck defines a POSA as a person who is "a clinician with a medical degree, or equivalent, and with a background or specialty in gastroenterology, gastrointestinal surgery, colorectal surgery, anesthesiology, or related field." (Merck Opening Br. 10 n.7; Resnick Decl. at ¶ 17.) Teva states a POSA "is a physician, clinician, and/or scientist specializing or having background in internal medicine, gastroenterology, or a related field, which could include background in or

relevant to the pharmacological effects of mu-opioid agonists and/or antagonists.” (Teva Opening Br. 8-9 (quoting Hyman Decl. ¶ 60).) Dr. Hyman, Teva’s expert, further provides, “This person would possess a relatively high level of skill, such as having at least a medical degree or Ph.D., and specialization or experience in treating, researching, or studying gastrointestinal-related conditions, symptoms, diseases or the like, associated with, for example, surgery, motility disorders, gastrointestinal obstructions, and/or opioid administration.” (*Id.* at 9.) Finally, Dr. Hyman states that a POSA “could have a lower level of formal education if that person has a higher degree of experience.” (*Id.*)

The Federal Circuit has made clear that the Court may consider the following factors in determining this issue:

- (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.

Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696-97 (Fed. Cir. 1983) (citation omitted). Additionally, the “starting point is based on the well-settled understanding that inventors are typically persons skilled in the field of the invention” *Phillips*, 415 F.3d at 1313.

The parties offer little to no explanation supporting their respective definitions, and, therefore, the Court is unable to fully evaluate the relevant factors. Merck’s definition fails to reference that a POSA would have specialized experience in “treating, researching, or studying gastrointestinal-related conditions, symptoms, diseases or the like” (Hyman Decl. ¶ 60.) At the Markman Hearing, however, Merck’s counsel stated, a POSA here is “a person with an MD or a PhD specializing in treating, researching, [or] studying [gastrointestinal]-related conditions,

symptoms, diseases, or the like.” (Markman Tr. 6:22-24.) Thus, Merck appears to have adopted Teva’s narrower definition, and consequently, the Court also adopts Teva’s definition of a POSA.

B. The Court Adopts Merck’s Construction of “Ileus” and Defers Finding on Indefiniteness

The parties differ in their proposed constructions of the term “ileus” in claim 17 of the ’030 Patent. (’030 Patent col. 32:6-7.) Merck contends the Court should adopt the definition included within the ’030 Patent, which is:

‘Ileus’, as used herein, refers to the obstruction of the bowel or gut, especially the colon. See, e.g., *Dorland’s Illustrated Medical Dictionary*, p. 816, 27th ed. (W.B. Saunders Company, Philadelphia 1988). Ileus should be distinguished from constipation, which refers to infrequent or difficulty in evacuating the feces. See, e.g., *Dorland’s Illustrated Medical Dictionary*, p. 375, 27th ed. (W.B. Saunders Company, Philadelphia 1988). Ileus may be diagnosed by the disruption of normal coordinated movements of the gut, resulting in failure of the propulsion of intestinal contents. See, e.g., Resnick, *J. Am. J. of Gastroenterology* 1997, 92, 751 and Resnick, *J. Am J. of Gastroenterology*, 1997, 92, 934.

(’030 Patent col. 2:6-18.) Teva asserts that the claimed term “ileus” is indefinite. (Teva Opening Br. 10, ECF No. 51.) Teva further provides that “[t]o the extent a construction may be offered, it means a ‘mechanical obstruction of the bowel or gut and not pseudo[-]obstruction, a gastrointestinal motility dysfunction, or constipation.’” (*Id.*) The Court addresses the parties’ proffered constructions in turn.

Merck contends the intrinsic evidence supports its construction of the term “ileus”. Specifically, Merck states that the Applicants served as the ’030 Patent’s lexicographers, and because they “expressly made clear what they meant by the term ‘ileus,’ and they used the term consistently in both the specification and the prosecution history” the Court should adopt its proposed construction. (Merck Opening Br. 14-15.) Merck further argues that the prosecution history supports the specification’s definition, because the “Applicants expressly distinguished

the use of alvimopan to treat ileus from the use of other opioid antagonists to treat ‘constipation’ during prosecution.” (*Id.* at 15 (citation omitted).)

Additionally, Merck concedes that constipation may be a secondary consequence of ileus, or “one of the constellation of symptoms of a patient having ileus.” (Merck Responsive Br. 6, ECF No. 64 (citing Hyman Dep. Tr. 77:15-17, 85:24-86:14).) Merck, however, contends that the condition of ileus and the condition of constipation are separate, and each have “different etiologies, diagnostic criteria, and treatments[,] and are experienced by patients in very different clinical contexts.” (*Id.* (citing Resnick Dep. Tr. 54:6-23).) Thus, according to Merck, “even if a patient diagnosed with ileus might, in some instance, also experience constipation as a secondary consequence, a POSA would not equate one condition for the other.” (*Id.* (citing Resnick Dep. Tr. 54:6-23, 62:10-21); *see also* Responsive Decl. of Jonathan Resnick (“Resnick Responsive Decl.”) ¶ 14, ECF No. 64-1).)

Merck also relies on an example within the specification (the “Example”), which describes a seventy-eight participant Phase II study. (’030 Patent col. 26:60-67 to 27:1-55.) In that study, patients were separated into three groups—one group was given twelve milligrams of the subject medication, another group was given two milligrams of the subject medication, and the third group was given a placebo. (*Id.*) The group that received the twelve-milligram dose measurably benefitted, demonstrated by improvement of the following study criteria: (1) “mean time to first flatus”; (2) “mean time to first bowel movement”; (3) “mean time to solid diet”; (4) “mean time to ready to discharge”; and (5) “mean time to actual discharge”. (*Id.* at col. 27:5-67 to 28:1-22.)

Merck avers that those figures, aside from demonstrating the subject medication is effective, underscore that alvimopan “reboots” the gastrointestinal system as a whole, rather than merely the “secondary consequence of constipation,” which is only “one of the constellation of

symptoms of a patient having ileus.”⁴ (Markman Hearing Tr. 62:8-11.) Thus, Merck argues the Court need not look beyond the intrinsic evidence to find support for its proffered claim construction. (Merck Opening Br. 16.)

Teva addresses each sentence in the specification—and Merck’s construction—separately. (See, e.g., Teva Responsive Br. 3, 4, 5, ECF No. 63.) Regarding the first sentence, Teva explains that the citation to Dorland’s Illustrated Medical Dictionary (27th ed. 1998) (“Dorland’s”) defines ileus expansively to include ileus subtypes, including both mechanical and functional obstructions.⁵ (Teva Opening Br. 11-12.) Teva notes that although Dorland’s includes both mechanical and functional obstructions, Dr. Resnick, Merck’s expert, disagreed with that definition, stating “‘ileus’ is a functional (rather than mechanical) obstruction . . .” (See Merck Responsive Br. 14-15 (quoting Markman Hearing Tr. 59:4-8).) Teva further contends the Applicants inserted ambiguity into the definition in the second sentence because the second sentence states ileus and constipation are different, but later in the patent, the Applicants stated that ileus could be “characterized by such symptoms as” “lack of flatus and/or stools”, which Dr. Hyman defines as constipation. (Teva Opening Br. 12 (citing ’030 Patent col. 7:55-58).)

⁴ Merck emphasized that the Example demonstrates that the mean time to first bowel movement using the subject medication took 2.72 days,

which is consistent with the idea that [it is] a reboot, effectively a reboot of the [gastrointestinal] tract. . . . In other words, [it is] not like a stool softener, where you take a stool softener and [twenty] minutes later you go to the bathroom [It is] a different modality. And so physicians would see that and be aware of that. So what [we are] seeing here is a resolution of the ileus.

(*Id.* at 15:15-23.)

⁵ According to Dr. Hyman, functional obstructions refer to when peristaltic movements are impaired, whereas mechanical obstructions refer to blockages that interfere with the passage of intestinal contents. (Hyman Decl. ¶¶ 43, 44.)

Thus, Teva argues “[t]his inconsistency renders the term ‘ileus’ indefinite because a POSA would not be reasonably certain whether treatment of ‘infrequent or difficulty in evacuating the feces,’ which is defined as constipation, but can result from obstruction of the gut, falls within the intended scope of the patent claims.” (Teva Opening Br. 12 (citing Hyman Decl. ¶¶ 66-67).) Further, Teva states the “permissive and non-limiting” language in the third sentence “does nothing to clarify the meaning of ‘ileus,’” and creates ambiguity because the cited references pertain to post-operative ileus, which is merely a subtype of ileus. (Teva Responsive Br. 5.)

Moreover, citing the prosecution history, Teva argues that the Applicants’ express disclaimer of constipation “clouds the meaning of ileus” because those disclaimers amounted to a condition that is “not pseudo[-]obstruction, a gastrointestinal motility dysfunction, or constipation.” (Teva Opening Br. 13, 15.) Teva contends this creates an irreconcilable issue because extrinsic evidence dictates a POSA would understand paralytic ileus and pseudo-obstruction to be the same condition, but claim 21 of the ’030 Patent explicitly references paralytic ileus. (*Id.* at 15; ’030 Patent col. 32:15-16.) Thus, Teva argues a POSA would be unable to discern the true scope of “ileus” within the ’030 Patent.

As a threshold matter, the Court finds that the claim at issue “is sufficiently definite to survive claim construction.” *Pharmastem Therapeutics, Inc. v. Viacell Inc.*, No. 02-148, 2003 U.S. Dist. LEXIS 877, at *2 n.1 (D. Del. Jan. 13, 2003). The Court, accordingly, declines to make a finding on indefiniteness at this juncture, and instead limits this opinion to construing the contested terms. *See Int’l Dev. LLC v. Richmond*, No. 09-2495, 2010 U.S. Dist. LEXIS 120133, at *17-18 (D.N.J. Nov. 12, 2010) (deferring the parties’ indefiniteness arguments until summary judgment because of “(1) the high burden of proof required to show indefiniteness and (2) its potentially dispositive, patent-invalidating nature”); *see also Pharmastem Therapeutics, Inc.*, 2003

U.S. Dist. LEXIS 877, at *2 n.1 (“While the court recognizes that a determination of indefiniteness is necessarily intertwined to some degree with claim construction, it is clear that the court must first attempt to determine what a claim means before it can determine whether the claim is invalid for indefiniteness.”).

The Court finds Merck’s definition persuasive because it is grounded in the intrinsic evidence and further supported by Dr. Resnick’s testimony and declarations. (*See, e.g.*, Resnick Responsive Decl. ¶¶ 8-13.) The Court further finds that Teva’s reading of the specification’s definition, with each sentence read in isolation and focusing primarily on the first sentence, is contrary to how a POSA would view the definition. (*Id.*) Instead, as Merck contends, and Dr. Hyman arguably agreed, a POSA would read the definition comprehensively, with the last two sentences qualifying the first sentence.⁶ (*See* Hyman Dep. Tr. 42:7-10, 43:16-17 (“I think . . . [a POSA] would primarily look to the first sentence because that provides the definition, and the other information I would view as qualifiers.”), ECF No. 63-8.)

The first sentence cites to Dorland’s, which provides an expansive and general definition of ileus. (’030 Patent col. 2:6-18; Dorland’s at 816.) The second sentence explicitly differentiates ileus from constipation, defining constipation as “infrequent or difficulty in evacuating the feces”, and again cites Dorland’s for that proposition. (*Id.* (citing Dorland’s at 375).) Finally, the last sentence—which references disruption of gut motility—states that such disruption results in failure

⁶ At the Markman Hearing, Merck also stated that a POSA reading the specification’s definition “would do the best [he or she] could to make sense of what the inventors were trying to convey. And that person would not look to find arguments that conflict. [He or she] would not look to create conflict. [He or she] would . . . try to understand the meaning.” (Markman Hearing Tr. 7:1-5.) Teva did not contest Merck’s assertion.

of propulsion of intestinal contents.⁷ The Court agrees that in reading the second and third sentences, a POSA would recognize that the Applicants were attempting to distinguish the severe condition of ileus, which may result in the complete failure of propulsion of intestinal contents, from constipation, which the Applicants defined as difficult or infrequent bowel movements.

Further, the third sentence cites to two articles Dr. Resnick authored, which specifically refer to ileus as a functional obstruction. (Jonathan Resnick et al., *Delayed Gastric Emptying and Postoperative Ileus After Nongastric Abdominal Surgery: Part I*, 92 Am. J. Gastroenterology 751 (1997) (“Resnick I”) ECF No. 54-3, Jonathan Resnick et al., *Delayed Gastric Emptying and Postoperative Ileus After Nongastric Abdominal Surgery: Part II*, 92 Am. J. Gastroenterology 934 (1997) (“Resnick II”), ECF No. 54-4.) Although those articles focus predominantly on postoperative ileus, Merck correctly notes that the articles, particularly Resnick I, discuss ileus generally. (See, e.g., Resnick I (referencing ileus and specifically defining postoperative ileus as “PI”).) The articles consider postoperative ileus a functional obstruction, and, in fact, Resnick I specifically states that “[i]leus . . . has been defined as a functional, nonmechanical obstruction of the bowel.” (*Id.*) Thus, the lexicography clearly includes functional obstructions, and the Court finds the Applicants’ seeming disclaimer of pseudo-obstruction does not preclude the Court from construing “ileus” at this phase.⁸

⁷ The Court is not persuaded by Teva’s contention that the third sentence should be discounted because the term “may” is non-limiting and fails to sufficiently clarify the term “ileus”. (See, e.g., Markman Hearing Tr. 60:22-25; Teva Responsive Br. 5.)

⁸ The Court also finds persuasive Dr. Resnick’s testimony that “a POSA would understand that even though pseudo[-]obstruction and ileus do share a broad common description as a functional obstruction, they remain distinct conditions with different etiologies, and a POSA would diagnose and treat them differently” (Responsive Resnick Decl. ¶ 30, ECF No. 64-1.)

“[T]he Federal Circuit has repeatedly expressed the view that ‘[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.’” *Baxter Healthcare Corp. v. Mylan Labs. Ltd.*, No. 14-7094, 2016 WL 1337279, at *4 (D.N.J. Apr. 5, 2016) (citing *Shire Dev., LLC v. Watson Pharms., Inc.*, 787 F.3d 1359, 1364 (Fed. Cir. 2015)). Here, Merck’s proposed construction is taken directly from the ’030 Patent specification and is supported by the intrinsic evidence. The Court, accordingly, finds the intrinsic evidence supports Merck’s construction, and construes the term “ileus” in the ’030 Patent in accordance with the definition contained within Patent’s specification itself. (*See* ’030 Patent col. 2:6-18.)

C. The Court Adopts Merck’s Construction of “Treating”

The parties also disagree on the meaning of the term “treating” within the ’030 Patent. Merck argues the Court should adopt the term’s plain and ordinary meaning, and no construction is required. (Merck Opening Br. 21.) Merck also provides that to the extent a construction is required, a POSA would understand “treating” to mean “reducing the duration of symptoms of”. *Id.* Merck argues the ’030 Patent supports this construction because the ’030 Patent consistently references the symptoms of ileus. For example, the ’030 Patent explains that the “‘effective amount’ refers to ‘an amount of [alvimopan] that may be therapeutically effective to [prevent or] treat the symptoms of . . . ileus’”. (*Id.* at 22 (quoting ’030 Patent col. 7:7-9).) The specification also includes a discussion of ileus-associated symptoms, such as “nausea, vomiting, lack of passage of flatus and/or stools, abdominal distention, and lack of bowel sounds.” (*Id.* at 22 (quoting ’030 Patent col. 7:57-59).)

Further, Merck again cites to the ’030 Patent’s Example, which considered the results of a seventy-eight participant study, and measured the subject medication’s effectiveness using the

following “end-points”: (1) “mean time to first flatus”;⁹ (2) “mean time to first bowel movement”; (3) “mean time to first solid diet”; (4) “mean time to first ready to discharge”; and (5) “mean time to actual discharge.” (’030 Patent col. 27:5-67 to 28:1-21.) Merck contends the Example supports its construction of “treating” because it illustrates the effectiveness of the subject medication via demonstrating the reduction of the duration of ileus’s symptoms. Thus, Merck argues the intrinsic evidence supports its construction of the term “treating”. (Merck Opening Br. 24.)

Teva contends “treating” in the ’030 Patent means “alleviating”. (Teva Opening Br. 17.) According to Teva, “alleviating” distinguishes between symptomatic treatment and treatment of the underlying condition itself. Specifically, Teva contends that because the Applicants clearly disclaimed constipation, “[a] POSA reviewing the ’030 [P]atent and its prosecution history would understand that Merck had disclaimed symptomatic treatment of ileus, leaving only ‘treatment’ of the disease itself.” (*Id.* at 18.) Teva, accordingly, argues that “[b]ecause the patent[] distinguish[es] between the symptoms and condition of ‘ileus,’ the construction of ‘treating’ should do so as well.” (*Id.*)¹⁰

The Court finds the intrinsic evidence supports Merck’s construction, and the Applicants’ differentiating ileus from the condition of constipation does not amount to a clear and

⁹ Merck emphasized that first flatus is a particularly important indicator of the resolution of ileus. Specifically, Merck stated, “lack of flatus is one of th[e] constellation of symptoms of ileus. And [it is] often referred to as surgeon’s music because the return of flatus can actually mark . . . ileus’s resolution and the beginning of return of normal [peristaltic] function of the gut.” (Markman Hearing Tr. 47:2-6.)

¹⁰ In support of this construction, Teva also introduces the term “management.” Teva provides that the management of a disease and the cure or amelioration of a disease have two separate meanings. (Markman Hearing Tr. 72:11-15.) Specifically, Teva contends that when one manages a condition, one is “treating the symptoms of that disease,” whereas when one alleviates a condition, one is “alleviating the underlying cause of that disease.” (*Id.* 74:4-7.)

unambiguous disclaimer of all symptomatic treatment. Specifically, the Court finds persuasive the '030 Patent's Example, which illustrates the subject medication's effectiveness via reduction of the duration of ileus symptoms, and thus those endpoints "serve as proxies for the treatment of ileus itself." (Markman Hearing Tr. 46:21-22.) The symptoms referenced include the reduction of time to first flatus, bowel movement, and solid diet. ('030 Patent col. 7:57-59.) The specification also explicitly lists symptoms that may "characterize" ileus—"nausea, vomiting, lack of passage of flatus and/or stools, abdominal distention[,] and lack of bowel sounds." ('030 Patent col. 7:57-59.) Thus, the intrinsic evidence itself considers the symptoms of ileus in discussing its characterization as well as its resolution.

The experts' testimony supports the intrinsic evidence. In fact, both experts provided that ileus is a condition that is characterized by its symptoms. Specifically, Dr. Hyman described ileus as "commonly present[ing] as a constellation of symptoms" (Hyman Dep. Tr. 77:2-3.) In referencing the Example, Dr. Resnick provided, "These clinical endpoints, reflecting the resolution of symptoms of ileus, serve as proxies for the resolution of the ileus itself, and are useful to a clinician because they are non-invasive and provide reliable indicators without a more invasive examination" (Resnick Responsive Decl. ¶ 41.) He further stated, "[i]leus is a clinical presentation" that cannot "be defined upon one distinct entity," but instead clinically presents as various symptoms. (*See* Resnick Dep. Tr. 145:5-146:2.) This testimony demonstrates that a POSA reading the '030 Patent would look to the resolution of ileus's symptoms in determining whether the condition itself was treated.

Teva contends that if the Court adopts Merck's proposed construction, the Court would effectively allow Merck to reclaim subject matter the Applicants clearly disclaimed. The Court, however, is guided by Dr. Resnick's testimony indicating that the condition of ileus is different

from the condition of constipation. Specifically, Dr. Resnick noted that the two conditions have different etiologies, diagnostic criteria, and patients experience the two conditions “in very different clinical contexts.” (Resnick Responsive Decl. ¶ 14.) Dr. Resnick also noted that “[a] gastroenterologist would approach diagnosis and treatment of constipation and ileus differently,” and explained that “a POSA would not treat constipation with a drug approved for ileus.” (*Id.*) Further, “[a] patient could suffer from constipation after the[] clinical endpoints (*e.g.*, after the first bowel movement), but a clinician would recognize that the ileus has been resolved.” (*Id.* ¶ 43.)

Finally, the Court is not persuaded that a POSA would understand “treating” in the context of the ’030 Patent in the detached way that Teva proposes; *i.e.*, as treating only the condition but not the symptoms of ileus.¹¹ The Court, accordingly, construes “treating” in the context of the ’030 Patent as “reducing the duration of symptoms of.”

IV. CONCLUSION

For the reasons discussed above, the Court adopts the foregoing construction of the claim terms. The Court will enter an Order consistent with this Memorandum Opinion.

s/ Michael A. Shipp

MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE

¹¹ In fact, Teva’s expert also appeared unable to support such a construction. (*See, e.g.*, Hyman Dep. Tr. 113:17-21 (“Q: Now, I’m trying to understand, are you offering the opinion that treating means alleviating the underlying disease state of . . . ileus without also managing the symptoms of ileus? A: I don’t think I’m saying that, no.”).)